
TRAINING AND COMMUNICATIONS

PARTICIPATION IN THE VOLUNTEER PROGRAM FOR PHARMACY STUDENTS

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PURPOSE This Guide specifies Center policy, procedures, and practices concerning participation of pharmacy students and Food and Drug Administration (FDA) professional employees, as preceptors, in the Volunteer Program for Pharmacy Students.

REFERENCES

- 21 CFR, Part 20. "Public Information"
 - 5 CFR, Part 308. "Volunteer Service"
 - MAPP 4510.2, "Clearance of Speeches, Articles, and Other Communication Materials."
 - 5 USC 3111.
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DEFINITIONS

- **Clerkship or Externship.** A program administered by schools of pharmacy which enables the pharmacy student to experience firsthand and to participate actively in the various work environments of the FDA pharmacist. Participation in this program by the pharmacy student may be a requirement for graduation.
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- **Preceptor.** For purposes of this guide, a preceptor is one who is responsible for the teaching, guidance, and supervision of the pharmacy student during the stay at the FDA. Preferably, the professional employee who acts as a preceptor should be a pharmacist. However, depending upon the criteria of participating schools of pharmacy, other professionals may serve as preceptors.
 - **Professional employee.** For purposes of this MAPP, a professional employee is one occupying a position that requires knowledge in a field of science or learning characteristically acquired through education or training equivalent to a bachelor's or higher degree, with a major in or pertinent to the specialized field, as distinguished from general education. The work of professional positions normally involves a demand for creative, analytical, evaluative, or interpretive application of specialized knowledge. It is further characterized by personal responsibility to keep abreast of, and exercise judgment and a broad perspective in the application of, an organized body of knowledge, which is constantly studied to make new discoveries and interpretations, and to improve the data, materials, and methods related to the field.
 - **Student.** For purposes of this MAPP, a student is an individual who is enrolled not less than half-time in a junior college, college, university or other accredited educational institution. An individual who is a student is deemed not to have ceased to be a student during an interim period between school years if the interim period is not more than 5 months and if such individual shows to the satisfaction of the agency that the individual has a bona fide intention of continuing to pursue a course of study or training in the same or different educational institution during the school semester (or other period into which the school year is divided) immediately after the interim period.
 - **Volunteer Program for Pharmacy Students.** A program designed to provide the pharmacy student, as part of his/her pharmacy school clerkship (or externship) program, an opportunity to become acquainted with the workings of a Federal agency, government regulations and rulemaking, and government administrative work. In addition, student participants can provide benefits to the agency with services such as conducting literature searches, or preparing summaries of findings upon completion of special projects assigned to them.

POLICY

- The Center for Drug Evaluation and Research (CDER) encourages the participation of professional employees and pharmacy students in the Volunteer Program for Pharmacy Students.
- Participation in the Volunteer Program for Pharmacy Students entails the choice by an FDA professional employee to be a preceptor to the student, and accept responsibility for supervision, training, and other professional activities during the student's stay at the agency. The FDA employee's supervisor must agree to the employee's accepting this responsibility.

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- Generally, student service at the agency should not exceed 40 hours per week, with hours compatible with those of the preceptor, or of another professional designated by the preceptor to supervise the student.
 - The pharmacy students that participate in this program are guests, and not employees, of FDA. Participation is during normal working hours and at FDA facilities. The student's length of stay at the agency may vary, depending upon the requirements of each pharmacy school. In general, this period of time is for 1-3 months, but may not exceed 1 year (2080 work hours). They do not receive salary nor subsistence payments during their stay at the agency. The pharmacy student should not be given access to confidential material and, therefore, must be closely supervised.
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RESPONSIBILITIES

- The initial request for participation in the Volunteer Program for Pharmacy Students occurs at the Division level. After appropriate documents are completed (Attachment A), they are forwarded to the Division Director and to the Deputy Office Director for approval. The Director of the Office exercises final approval authority regarding participation in the Volunteer Program for Pharmacy Students. Those Divisions interested in participating in this program should follow the procedures outlined below under part 6, "PROCEDURES."
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PROCEDURES

- Divisions interested in participating in the Volunteer Program for Pharmacy Students are responsible for understanding and following these procedures:
 1. A Student Volunteer Service Agreement should be prepared by the originating office (Attachment A). This document explains the role of the Student Volunteer, the conditions of association with FDA, and contains agreement forms for the Student Volunteer, the school of pharmacy, and the FDA.
 2. Divisions should prepare a written Proposed Program for a Student Volunteer that is acceptable to the Division, the student's school of pharmacy, and the student (see Attachment A, Section I.7). It should then be incorporated into the Student Volunteer Service Agreement.
 3. The Student Volunteer Service Agreement, with the proposed program, should be submitted to the Division Director and the Deputy Office Director for their approval.

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4. Upon approval (step 3, above), a copy of the Student Volunteer Agreement and the proposed program should be forwarded to the pharmacy student for signature and the signature of the approving educational institution official. These forms should be returned to the appropriate FDA Division at least two weeks before the student's arrival at FDA.
 5. Signatures of the FDA preceptor, the Division Director, the Deputy Office Director, and the Office of Human Resources and Management Services should then be obtained. Copies of the signed agreement should be provided to the pharmacy student, the pharmacy school or university representative, the Administrative Officer of the FDA office, the Division, and the Office of Human Resources and Management Services (HFA-423).
 6. Following standard procedures, the Administrative Officer for the Office will prepare a Request for Personnel Action (SF-52) upon the student's arrival and departure. A Notification of Personnel Action (SF-50) will be issued by the Office of Human Resources and Management Services upon approval of the SF-52.
 7. Upon completion of the student volunteer's service, the preceptor should prepare a written evaluation of the Student Volunteer's performance (See Attachment B). This evaluation should include a description of the Student Volunteer's assignments, any meetings the Student Volunteer was required to attend, and activities in which the Student Volunteer participated. In addition, the Student Volunteer should provide a written evaluation of the clerkship at FDA. The latter evaluation may be required by the student's school of pharmacy.
 8. Copies of the preceptor's and the Student Volunteer's evaluations should be submitted to the Office of Human Resources and Management Services (HFA-423) for placement in the student's personnel file. Copies of the evaluations may also be filed at the Division level.
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EFFECTIVE DATE

This guide is effective upon date of publication.

Attachment A

STUDENT VOLUNTEER SERVICE AGREEMENT

Section I - Assignment Data

1. Student's Name:
2. Academic Discipline or Course of Training:
3. Educational Institution/Academic Level:
4. Assignment Location (organization and duty station):
5. Proposed length of service:
6. Proposed tour of duty (hours per week):
7. Proposed Program for Student Volunteer: (To be developed by the participating Division and subsequently incorporated here. Below is an example.)
 - a. The Student Volunteer will provide a benefit to the Division by providing staff members with the results of literature searches in the form of scientific data, by providing staff members with summaries of findings upon completion of each special project, and by participating in other professional activities. (Note: the Student Volunteer will be closely observed so that he/she will not be exposed to confidential material during his/her stay at the FDA.)
 - b. The Division will provide a benefit to the student participant by offering the following:
 - FDA/CDER orientation
 - Division orientation
 - Library orientation
 - Introduction to evaluation functions with emphasis on safety/effectiveness/labeling
 - Miscellaneous (drafting letters/memos; proofreading and editing nonconfidential material)

The above will be provided by Division staff members. Visits to other divisions or other places of professional interest will be arranged by the student's preceptor as time permits.

Section II - Educational Institution Agreement

I certify that _____ is a student in good standing and that the FDA work assignment and scheduled hours of work are approved as appropriate for the course of study or training that he/she is pursuing. The student (will) (will not) be given credit (academic or other) for the work assignment.

I understand that a record of the student's attendance and an evaluation of his/her performance will be provided to this institution when the work assignment is completed.

(Signature of Approving Educational
Institution Official)

(Date)

(Typed Name)

(Title)

(Educational Institution)

(Address)

(Phone Number)

Section III - Volunteer Student Agreement

I have read the attached statement of duties and agree to perform the assignment as described in Section 1.

I understand that:

I am to receive no pay for services rendered;

I am not considered to be a Federal employee for any purpose other than for purposes of the Federal Tort Claims provisions published in 28 U.S.C., 2671 through 2680. and Title V, U.S.C., Chapter 81, relative to compensation for injuries sustained during the performance of work assignments;

I am to conduct myself with honesty and integrity in the performance of my duties;

I am to observe all rules of safety in the performance of my duties;

I am to consciously safeguard Government business which is not for public information. As a Student Volunteer, I may have access only to information available under the Agency's Freedom of Information regulations and/or derived from work I have been personally involved in or developed myself. As a Student Volunteer, I would have the right to publish or otherwise divulge the work I have performed. However, I agree to obtain advance clearance from the Food and Drug Administration in accordance with procedures which apply to FDA employees before I seek public disclosure of such information through publication or speeches, or otherwise divulge such information.

I further understand that:

This agreement may be terminated at any time by myself, my educational institution, or the Food and Drug Administration; and that,

A record of my attendance and an evaluation of my performance will be provided to me and my educational institution when my work assignment is completed.

I have read the above conditions and guidelines governing my association with the Food and Drug Administration as a Student Volunteer and have had an opportunity to discuss and ask questions on these matters. I agree to comply with the conditions and guidelines.

(Student Volunteer)

(Date)

Section IV - FDA Agreement

The Food and Drug Administration agrees to accept the volunteer services described in Section I.

The Student Volunteer will be supervised by an FDA Preceptor. A record of attendance and a written evaluation of the student's performance will be provided to the student and the educational institution at the end of the assignment.

(Signature, Deputy Director, Office of	Date

(Director, Division of	Date

(FDA Employee/Preceptor)	Date

(Office Human Resources and Management Services)	Date

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Attachment B

STUDENT VOLUNTEER SERVICE EVALUATION

To: Office of Human Resources and Management Services

From: (Type or print name and title of preceptor)

Student Volunteer's Name (First, MI, Last)

Service Period Covered
from to

Service Location (Field Office/Center/Division)

1. Brief description of work assignment(s), including meetings
attended, other activities

2. Skills and knowledge gained during this service period

3. General knowledge of Food and Drug Administration acquired during this service period

Originator: Management Services, Office of Management
11/1/95

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4. Preceptor's comments

5. Preceptor's signature